REMARKS

Interview request

Applicants respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at 858 720 5133.

The Interview of January 31, 2006

Applicants thank the Examiner for the courteous and helpful telephonic interview of January 31, 2006, in which issues regarding the pending claims was discussed (see Interview Summary sheet attached to the OA). Applicants note that in the instant OA pending claims 31 to 35, 51 and 55 to 62 are not rejected under sections 102 or 103.

Status of the Claims

Pending claims

Claims 31 to 43, 51, and 55 to 63 are pending.

Claims canceled and added in the instant amendment

Claims 58 and 60, without prejudice or disclaimer, and claims 64 to 68 are added. Thus, after entry of the instant amendment, claims, will be pending and under consideration. Thus, after entry of the instant amendment, claims 31 to 43, 51, 55 to 57, 59 and 61 to 68 will be pending and under consideration.

Outstanding Rejections

Claims 31 to 43, 51 and 55 to 57 remain rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 to 8 of U.S. Patent No. 6,379,886 B1.

Claims 31 to 43, 51 and 55 to 63 are newly rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over pending claims 13 to 22 of co-pending U.S. Patent Application Serial No. 11/126,662.

Claims 31 to 43, 51 and 55 to 63 are rejected under 35 U.S.C. §112, second paragraph.

Claims 36 to 43 and 63 are newly rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Lesneiwski et al., WO 93/06247 A1, published April 01, 1993, in view of Lambert, S., U.S. Patent 5,164,299, issued November 17, 1992.

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims.

Support for the Claim Amendments

The specification sets forth an extensive description of the invention in the amended claims. For example, support for diagnostic reagents using a synthetic peptide having a molecular weight of 1,000 to 5,000, can be found, inter alia, on page 3, lines 7 to 23. Accordingly, no new matter is added by the instant amendment.

Issues Under Obviousness-Type Double Patenting

U.S. Patent No. 6,379,886

Claims 31 to 43, 51 and 55 to 57 remain rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 to 8 of U.S. Patent No. 6,379,886 B1. To address this provisional rejection, an appropriate Terminal Disclaimer addressing this issue is attached.

USSN 11/126,662

Claims 31 to 43, 51 and 55 to 63 are newly rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over pending claims 13 to 22 of co-pending U.S. Patent Application Serial No. (USSN) 11/126,662.

Applicants elect to hold this issue in abeyance until such time claims are held allowable.

Issues under 35 U.S.C. §112, second paragraph

Claims 31 to 43, 51 and 55 to 63 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The instant amendment addresses the Office's concerns.

Issues under 35 U.S.C. §103(a)

Claims 36 to 43 and 63 are newly rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Lesneiwski et al., WO 93/06247A1, published April 01, 1993 (hereinafter "Lesneiwski"); in view of Lambert, S., U.S. Patent 5,164,299, issued November 17, 1992 (hereinafter "Lambert").

A *prima facie* case of obviousness requires that three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20USPQ2d 1438 (Fed. Cir. 1991); MPEP §2143. If any one of these three criteria is not met, a *prima facie* case of obviousness has not been established. As presented below, Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

The amended claims

After entry of the instant amendment, claim 36 is drawn to diagnostic reagents for hepatitis C virus (HCV) infection comprising a solid phase sensitized with (a) a genetic recombinant HCV antigen having a molecular weight of 10,000 or more and (b) one or more conjugated HCV antigens, wherein the conjugated HCV antigen comprises a synthetic peptide conjugated with a carrier protein and the synthetic peptide has a molecular weight of less than 10,000.

Lesneiwski

Lesneiwski discloses a confirmation assay comprising a use of a recombinant HCV C100-3 polypeptide and synthetic peptides, p1684, p1694 and p1866. The Office notes that Lesneiwski is defective in that it does not teach conjugating a less than 10,000 MW antigen peptide with carrier protein (see page 6, last line of paragraph 14, of the OA).

In contrast to the instant invention, in Lesneiwski's assay HCV synthetic peptides (a C100-3 polypeptide and p1684, p1694 and p1866) are separately coated onto polystyrene beads (please see page 18, lines 26 to 29, of Lesneiwski). Lesneiwski is defective in that it does not describe use of

an HCV synthetic peptide conjugated with a carrier protein. Therefore, Lesneiwski does not disclose the features of "a solid phase sensitized with (a) a genetic recombinant HCV antigen having a molecular weight of 10,000 or more and (b) one or more conjugated HCV antigens, wherein the conjugated HCV antigen comprises a synthetic peptide conjugated with a carrier protein, and the synthetic peptide has a molecular weight of less than 10,000" as in amended claim 36 of the present invention.

Applicants note that while Lesneiwski describes many alternative ways to conjugate a synthetic peptide to a solid phase, see e.g., page 34, Table 4, of Lesneiwski, none of these many alternative embodiments describe or suggest any alternative to direct conjugation of a synthetic peptide to a solid phase, and Lesneiwski provides no motivation to attach a synthetic peptide to a solid phase in any manner other than by direct attachment.

Lambert

Lambert was cited to cure the defect(s) in Lesneiwski (see page 6, paragraphs 15 and 16, of the OA). However, Applicants respectfully aver that this combination of cited art does not suggest or teach the claimed invention.

Lambert discloses "a solid phase heterogeneous or homogeneous immunoassay to detect or quantitate an analyte in a liquid sample which comprises: a) reacting binding reagent, immobilized on a solid phase, with sample; and b) determining the extent of binding which occurs in step a); wherein the immobilized binding reagent is a mixture of carrier-conjugated and unconjugated binding reagent in which the ratio of carrier-conjugated binding reagent to unconjugated binding reagent is in the range from 1:19 to 19:1" (see, e.g., claim 1; column 8, lines 44 to 55, of Lambert). Lambert very specifically states in the first line of its Summary that the invention is "[a] combination of unconjugated and carrier-conjugated forms of one member of a pair of binding reagents is used in the preparation of the solid phase component of an assay that can then be used to detect and quantify an analyte (emphasis added) (see column 2, lines 46 to 50, of Lambert).

Lambert also discloses that a mixture of a recombinant Hepatitis B core antigen conjugated with BSA (BSA-conjugated rHBcAG) and an unconjugated rHBcAG is sensitized on a solid phase (Example 1). The antigen used for the BSA-conjugated rHBcAG is the same antigen used for unconjugated rHBcAG. Example 1 of Lambert states that, by using such a solid phase sensitized

with a mixture of a BSA-conjugated rHBcAG and an unconjugated rHBcAG, it will be possible to lower the incidence of false positive results in negative samples and to improve in assay sensitivity when positive samples are diluted.

However, Lambert does not disclose conjugating an antigen, which is different from an unconjugated antigen, with a carrier protein such as BSA. Therefore, Lambert does not disclose the features of "a solid phase sensitized with (a) a genetic recombinant HCV antigen having a molecular weight of 10,000 or more and (b) one or more conjugated HCV antigens, wherein the conjugated HCV antigen comprises a synthetic peptide conjugated with a carrier protein and the synthetic peptide has a molecular weight of less than 10,000" in claim 36 of the present invention.

Accordingly, Lambert does not cure this defect in Lesneiwski – Lambert does not teach conjugating a less than 10,000 MW antigen peptide with carrier protein, and Lambert does not describe use of an HCV synthetic peptide conjugated with a carrier protein. Because Lambert does not cure this defect in Lesneiwski, this combination of cited art does not suggest or teach the instant claimed invention.

Since neither Lesneiwski nor Lambert, nor their combination, discloses the features of claim 36, it is clear that the independent claim 36 is not obvious from either citation or from a combination of the citations.

Lesneiwski does not describe the technical problem that when a solid phase is sensitized with a recombinant polypeptide and synthetic peptide(s) directly, detection sensitivity lowers. Nor does Lesneiwski describe the technical problem that when a solid phase is sensitized with a recombinant polypeptide and synthetic peptide(s) directly, long-term storage stability decreases.

Lambert discloses that, by using a solid phase sensitized with a mixture of a BSA-conjugated rHBcAG and an unconjugated rHBcAG, it will be possible to lower the incidence of false positive results in negative samples and to improve in assay sensitivity when positive samples are diluted. However, Lambert does not describe the technical problem of using a solid phase sensitized with a recombinant polypeptide and synthetic peptide(s) directly, namely such a reagent lowers detection sensitivity and decreases long-term storage stability of the reagent.

On the other hand, Examples 5 and 6 of the present specification show the comparison of the reagent used in the claimed invention, which is prepared by the conjugation of synthetic peptide(s)

with BSA, with a reagent prepared by direct sensitization. Example 5 clearly shows that the reagent of the present invention has a better detection sensitivity of HCV antibodies than a reagent prepared by direct sensitization. Example 6 also shows that the reagent of the present invention has better long-term storage stability than a reagent prepared by direct sensitization. These prominent effects of the present invention are beyond the expectation range of the citations.

Accordingly, because none of the cited references Lesneiwski or Lambert alone or in any combination teach, suggest or provide motivation for the claimed invention (after entry of the instant amendment), a *prima facie* case of nonobviousness has not been made, and this rejection under section 103 can be properly withdrawn.

CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully aver that the Examiner can properly withdraw the rejection of the pending claims under 35 U.S.C. §103(a) and 35 U.S.C. §112, second paragraph. Applicants respectfully submit that all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 322732000401. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone the undersigned at 858 720 5133.

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Respectfully submitted,

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